

K12596 #112

Endoscopy
Smith & Nephew, Inc.
150 Minuteman Road
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510(k) Summary

NOV 20 2012

Smith & Nephew Interference Screw Systems Instruments

1. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road
Andover MA, 01810

2. Company Contact

Sean Reynolds
Manager, Regulatory Affairs
Phone: (978) 749-1173
FAX: (978)-749-1443

3. Device Name

Trade Name: Arthroscopic Surgical Instruments—Interference Screw Systems
Common Name: Smooth or threaded metallic bone fixation fastener
Classification Name: Smooth or threaded metallic bone fixation fastener

4. Predicate Devices

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems described in this premarket notification are considered substantially equivalent to the cleared devices identified in **Table 1**.

Table 1: Summary of Predicate Device Clearance Information

Description	510(k)	Clearance Date
Smith & Nephew PEEK Interference Screws	K083226	1/30/2009
Smith & Nephew Biosure PK Interference Screw	K083635	1/30/2009
Smith & Nephew HA-PLA Interference Screw	K002274	3/7/2001
Smith & Nephew Cannu-Flex Interference Screws	K921481	8/24/1993
Smith & Nephew Bioabsorbable Interference Screw	K984320	1/28/1999
Smith & Nephew RCI Fixation Screws	K992945	9/1/1999

When compared to previously cleared device specific instruments, the proposed instruments utilize the same raw materials, manufacturing processes, and have the same intended use and nature of body contact.

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems are similar in design, function and intended use to competing interference screw surgical instrumentation on the market.

5. Description of Device

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems are accessory devices and take on the classification of the device(s) with which they are used. The Drivers, Taps, Screw Starters, and Routers are all manufactured from medical grade Stainless Steel.

6. Intended Use

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

7. Comparison of Technological Characteristics

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems are substantially equivalent in design, materials, and intended use to previously cleared device specific instruments. The subject device specific arthroscopic surgical instruments are used in conjunction with the interference screw systems detailed in **Table 1**.

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems do not incorporate any new technological characteristics as compared to legally marketed devices. The instruments which are the subject of this submission are existing instruments that are currently marketed in the United States as Class I devices. The purpose of this submission is to bring those instruments into compliance with FDA's current policy. The recommended surgical techniques associated with the predicate device systems have not been changed or modified as a result of this 510(k).

8. Summary Performance Data

The subject device specific arthroscopic surgical instruments associated with the Smith & Nephew Interference Screw Systems have the same intended use, technological and performance characteristics as the legally marketed predicate devices. The product designs are in conformance with the recognized consensus standards identified in this submission and do not raise any new issues of safety and efficacy.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Smith & Nephew, Incorporated
% Mr. Sean Reynolds
Manager, Regulatory Affairs
150 Minuteman Road
Andover, Massachusetts 01810

Letter Dated: November 20, 2012

Re: K122596

Trade/Device Name: Arthroscopic Surgical Instruments – PEEK Interference Screws
Systems

Regulation Number: 21 CFR 888.3040

Regulation Name: Smooth or threaded metallic bone fixation fastener

Regulatory Class: Class II

Product Code: HWC, MBI, MAI

Dated: August 20, 2012

Received: August 24, 2012

Dear Mr. Reynolds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K122596

Device Name: Arthroscopic Surgical Instruments—PEEK Interference Screws

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

The Smith & Nephew PEEK Interference Screws are indicated for the reattachment of ligament, tendon or soft tissue to bone for the following:

Shoulder:

Bankart Repair, Anterior Shoulder Instability, SLAP lesion repairs, Capsular shift or capsulolabral reconstruction, Acromioclavicular separation repairs, Deltoid repairs, Rotator cuff tear repairs, Biceps tenodesis

Foot/Ankle:

Hallux Valgus, Lateral stabilization, Medial stabilization, Achilles Tendon repair/recon, Midfoot reconstruction, Metatarsal Ligament/tendon repair, Bunionectomy, Flexor Hallucis Longus repair, Tendon Transfers.

Elbow/Hand/Wrist:

Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Recon, Lateral Epicondylitis Repair, Scapholunate Ligament Recon, Tendon Transfers, Carpometacarpal Joint Arthroplasty, Carpal Ligament Recon/Repair

Knee:

Medial or Lateral Collateral ligament, Posterior oblique ligament, Vastus medialis obliquus advancement, iliotibial band tenodesis, ACL Repairs, MCL Repairs, LCL Repairs, Patellar tendon repair, Posterior Oblique ligament repair.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2012.11.19

14:11:24 -05'00'

Indications for Use510(k) Number (if known): K122596

Device Name: Arthroscopic Surgical Instruments— BIOSURE PK Interference Screws

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

The Smith & Nephew BIOSURE PK Interference Screws are indicated for the reattachment of ligament, tendon, soft tissue, or bone to bone during cruciate ligament reconstruction surgeries of the knee. All screws with a diameter of 9mm or less and a length of 25mm or less are also intended for use in the following procedures:

Knee

- ACL Repairs
- PCL Repairs
- Extra-capsular repairs
 - Medial collateral ligament
 - Lateral collateral ligament
 - Posterior oblique ligament
- Patellar realignment and tendon repairs
 - Vastus medialis obliquous advancement
- Iliotibial band tenodesis

Shoulder

- Capsular stabilization
 - Bankart repair
 - Anterior shoulder instability
 - SLAP lesion repairs
 - Capsular shift or capsulolabral reconstructions
- Acromioclavicular separation repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

Foot and Ankle

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions

- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy
- Flexor Hallucis Longus (FLH)
- Tendon Transfers

Elbow, Wrist, and Hand

- Biceps tendon reattachment
- Ulnar or radial collateral ligament reconstructions
- Lateral epicondylitis repair
- Scapholunate ligament reconstruction
- Tendon Transfers
- Carpometacarpal Joint Arthroplasty
- Carpal Ligament Reconstruction

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

2012.11.19
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Indications for Use510(k) Number (if known): K122596

Device Name: Arthroscopic Surgical Instruments— HA-PLA Interference Screw

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

The Smith & Nephew HA-PLA Interference Screw is indicated for fixation of bone-tendon-bone or soft tissue grafts during anterior or posterior cruciate ligament reconstruction surgery.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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-05'00'

Indications for Use

510(k) Number (if known):

K122596

Device Name: Arthroscopic Surgical Instruments—CANNU-FLEX Interference Screws

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

The Cannu-Flex Silk Screw is an Interference Screw, indicated for tendon/ligament graft fixation.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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Indications for Use

510(k) Number (if known):

K122596

Device Name: Arthroscopic Surgical Instruments—Bioabsorbable Interference Screws

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use.

1. The Bioabsorbable Interference Screw is used for fixation of bone-tendon-bone or soft-tissue grafts during Anterior and/or Posterior Cruciate Ligament (ACL/PCL) reconstruction.
2. The screw is indicated for single use only.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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Anton E. Dmitriev, PhD
Division of Orthopedic Devices

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Indications for Use

510(k) Number (if known):

K122596

Device Name: Arthroscopic Surgical Instruments— RCI Fixation Screws

Indications for Use:

Smith & Nephew Arthroscopic Surgical Instruments—Interference Screw Systems are surgical instruments used in arthroscopic surgery to facilitate the implantation of Interference Screw Systems for their cleared Indications for Use:

RCI Fixation Screws are used for interference fixation of Bone-Tendon-Bone or soft tissue grafts in anterior or posterior cruciate ligament reconstruction.

Prescription Use X

AND/OR

Over-The-Counter Use

(Per 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

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